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PATENT
Attorney Docket No. 021186-001520US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

JOHN MILLER *et al.*

Application No.: 10/692,424

Filed: October 22, 2003

For: BALLOON CATHETER

Confirmation No. 8368

Examiner: HOOK, JAMES F

Technology Center/Art Unit: 3754

TRANSMITTAL OF AMENDED APPELLANTS' BRIEF UNDER 37 CFR §41.37

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The attached Amended Appeal Brief is being filed in response to the U.S. Patent Office Communication mailed on July 31, 2006. The Amended Brief corrects the informalities noted in the Communication.

The Appeal Brief fee has been paid pursuant to 37 CFR §41.20. While no fees are believed to be due at this time, the Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application to Townsend and Townsend and Crew Deposit Account No. 20-1430.

Respectfully submitted,

Date: 8/30/2006

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Sir:

Appellant offers this Appeal Brief in furtherance of the Notice of Appeal and Pre-Appeal Brief Request for Review, both of which were filed on December 12, 2005; and in furtherance to Notice of Panel Decision from Pre-Appeal Brief Review mailed March 2, 2006. Appendix A, attached hereto, contains a copy of all claims pending in this case. Appendix B, attached hereto, is marked the evidence appendix. Appendix C, attached hereto, is marked the related proceeding appendix.

TABLE OF CONTENTS

1. REAL PARTY IN INTEREST

All right, title, and interest in the subject invention and application are assigned to Concentric Medical, Inc., having offices at 1380 Shorebird Way, Mountain View, California 94043. As such, Concentric Medical, Inc. is the real party in interest.

2. RELATED APPEALS AND INTERFERENCES

No other appeals or interferences are known which will directly affect, or be directly affected by, or have bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 1-9 are currently pending and are the subject of this appeal. No other claims are pending.

Claims 1-8 were originally presented in the application. Claims 1-8 were amended by preliminary amendment mailed January 8, 2004. Claims 1-8 were amended and claim 9 was added in Appellant's response mailed March 15, 2005. A Final Office Action was mailed on June 15, 2005. Appellant submitted a response to the Final Office Action, Appellant's response to the Final Office Action was mailed on July 19, 2005. An Advisory Action was mailed on August 8, 2005. Appellant filed a Pre-Appeal Brief Request for Review on December 12, 2005. Pursuant to the Notice of Panel Decision from Pre-Appeal Brief Review mailed March 2, 2006, claims 1-9 remain rejected and the application remains under appeal because there is at least one actual issue for appeal.

As such, the status of the claims is as follows:

Claims 1, 2, 6, and 7 stand rejected under 35 U.S.C. § 103(a) as being obvious over Steen (U.S. Patent No. 6,213,995) in view of Mische (U.S. Patent No. 5,052,105).

Claims 1-9 stand rejected under 35 U.S.C. § 103(a) as being obvious over Samson (U.S. Patent No. 6,186,978) in view of Mische (U.S. Patent No. 5,052,105).

4. STATUS OF AMENDMENTS

No amendment to the claims was filed subsequent to the Final Office Action mailed June 15, 2005. A copy of all the pending claims involved in the present appeal is provided in Appendix A attached hereto.

Appellant submitted a response to the Final Office Action requesting reconsideration of the rejections set forth in the Final Office Action, but no amendment to the claims after the Final Office Action was requested by Appellant (see Appellants response, mailed July 19, 2005). Appellant points out that a Terminal Disclaimer was filed in Appellant's response (After Final Rejection), mailed July 19, 2005. This Terminal Disclaimer was filed in response to a Double Patenting rejection over commonly owned U.S. Patent No. 6,702,782, the Double Patenting rejection was made in the Final Office Action mailed June 15, 2005. In the Advisory Action mailed August 8, 2005, the Double Patenting rejections were deemed overcome by the filing of the approved Terminal Disclaimer.

Additionally, as stated in Section 3 above, a Pre-Appeal Brief Request for Review was filed on December 12, 2005. Pursuant to the Notice of Panel Decision from Pre-Appeal Brief Review mailed March 2, 2006, claims 1-9 remain rejected and the application remains under appeal because there is at least one actual issue for appeal.

While these actions after Final Rejection (i.e., Appellant's response mailed July 19, 2005; Terminal Disclaimer; Pre-Appeal Brief Request for Review) may not necessarily be considered an "amendment" filed subsequent to Final Rejection, Appellant mentions them here so that there is no confusion as to the status of any paper filed after Final Rejection.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates generally to medical devices and more particularly to a balloon catheter having at least two lumens. U.S. Application No. 10/692,424, filed October 22, 2003 (hereinafter "Application"), page 1, lines 9-10. One of the lumens is a large working lumen. *Id.* at page 1, line 10. The inventive catheter is useful, for example, as a guide catheter or a micro catheter and may be used in a variety of therapeutic and diagnostic procedures variously in the neuro-, peripheral, and coronary vasculature. *Id.* at page 1, lines 10-13. In particular, it has value in treating neurovascular embolic strokes in combination with other devices which are delivered to the stroke site through the working lumen. *Id.* at page 1, lines 13-15. The remainder of the lumens typically are used to inflate and to deflate the balloon. *Id.* at page 1, line 15. It is highly preferable that the balloon or inflatable member be situated in a recess in the outer wall of the inventive catheter. *Id.* at page 1, lines 15-17. The distal end of the catheter past the balloon may be tapered. *Id.* at page 1, line 17. The inventive device has a very low profile as compared to other catheters of the balloon catheter genre. *Id.* at page 1, lines 18-19. It may include other features such as variable stiffness along the axis of the device and anti-kinking components. *Id.* at page 1, lines 19-20. The balloon may be compliant in nature. *Id.* at page 1, line 20.

The appealed claims are directed to a catheter according to the present invention. Claim 1, the only independent claim, describes a catheter (102) comprising a catheter body (116) including at least one polymeric tubular member (300) and a braided tubular structure comprising a plurality of component tubular members (200) each having longitudinal lumens (302), woven radially in and out to form the braided tubular structure, wherein the braided tubular structure is embedded in a wall of the polymeric tubular member (300). These elements are discussed in the Application, for example, at page 3, lines 4-8; page 4, lines 8-13; page 4, line 27, to page 5, line 4; page 9, line 15, to page 10, line 14; page 17, line 1, to page 18, line 15; Figs. 1, 2A-2B, and 8-14.

The catheter of the invention provides advantages over existing devices, for example, in that inflation media can be passed through the lumens of each of the braided tubular structure embedded in the catheter wall and can be used for inflating/deflating a balloon or

inflatable member on the catheter body, thereby providing a balloon catheter with a large working lumen. Application page 4, lines 8-13; page 4 line 27, to page 5, line 4. For example, depended claim 8 further recites that the plurality of component tubular members (220) longitudinal lumens (302) are fluidly connected to a plenum (222) at least one of the distal and proximal ends. Dependent claim 9 further includes a balloon (112) on the catheter body (116) connected to exchange inflation media through the lumens (302) of the braided tubular structure. These elements are discussed in the Application, for example, at page 3, lines 4-8; page 4, lines 8-13; page 4, line 27, to page 5, line 4; page 9, line 15, to page 10, line 14; page 17, line 1, to page 18, line 15; Figs. 1, 2A-2B, 4A-4E, and 8-14.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1, 2, 6, and 7 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Steen (U.S. Patent No. 6,213,995) in view of Mische (U.S. Patent No. 5,052,105).

Whether claims 1-9 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Samson (U.S. Patent No. 6,186,978) in view of Mische (U.S. Patent No. 5,052,105).

7. GROUPING OF THE CLAIMS

Appellant submits that the claims do not stand or fall together. Only claims 1-6 stand together. Dependent claim 8 stands by itself. Dependent claim 9 stands by itself.

Claim 1 broadly recites a catheter comprising a catheter body including at least one polymeric tubular member and a braided tubular structure comprising a plurality of component tubular members each having longitudinal lumens, woven radially in and out to form the braided tubular structure, wherein the braided tubular structure is embedded in a wall of the polymeric tubular member.

Depended claim 8 further requires where said plurality of component tubular members longitudinal lumens are fluidly connected to a plenum at least one of the distal and proximal ends. This additional novel and non-obvious element supports the separate and independent patentability of this claim.

Dependent claim 9 further includes a balloon on the catheter body connected to exchange inflation media through the lumens of the braided tubular structure. This additional novel and non-obvious element supports the separate and independent patentability of this claim.

8. ARGUMENT

A. Whether claims 1, 2, 6, and 7 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Steen (U.S. Patent No. 6,213,995) in view of Mische (U.S. Patent No. 5,052,105).

In the Final Office Action mailed June 15, 2005, claims 1, 2, 6, and 7 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Steen (U.S. Patent No. 6,213,995) in view of Mische (U.S. Patent No. 5,052,105). Appellant respectfully traverses this rejection.

The present rejection does not establish *prima facie* obviousness under 35 U.S.C. § 103 and MPEP §§ 2142-2143. The Examiner bears the initial burden to establish and support *prima facie* obviousness. *In re Rinehart*, 189 U.S.P.Q 143 (CCPA 1976). To establish *prima facie* obviousness, three basic criteria must be met. MPEP § 2142. First, the Examiner must show some suggestion or motivation, either in the prior art references or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings so as to produce the claimed invention. MPEP § 2143.01. Secondly, the Examiner must establish that there is a reasonable expectation of success for the modifications. MPEP § 2142. Thirdly, the Examiner must establish that the prior art references, alone or in combination, teach or suggest all the claim limitations. MPEP § 2143.03.

Appellant respectfully submits that a *prima facie* case of obviousness has not been met in the present case. In particular, Appellant submits that the Examiner has failed to identify the requisite suggestion or motivation to replace elements in the braid structure of Steen with hollow microtubes taught by Mische.

Appellant generally agrees with the Examiner's characterization of Steen, but disagree with the characterization of Mische or that any reasonable combination of the cited references would produce the claimed invention. Steen teaches an electrode catheter having a central lumen and a braid reinforcement structure within the catheter wall. The braid structure of Steen includes a braided combination of 1) structural elements, which provide stiffness and rigidity to the catheter; and 2) solid signal transmitting elements, including either electrically

insulated, solid metal conductive wires, or solid optical fibers (e.g., glass). As acknowledged by the Examiner, nowhere does Steen teach or suggest a braided tubular structure comprising a plurality of component tubular members, as required by claim 1. See, e.g., Final Office Action dated June 15, 2005, page 3.

The Examiner attempts to remedy the deficiency of Steen, by combining the teachings of Steen with those of Mische. In particular, the Examiner argues the following:

> The patent to Mische discloses that it is old and well known in the art to substitute hollow conductive tubes 19 in place of conductive wires 14, and that such can be used interchangeably in catheters where such are equally useful conductive means. It would have been obvious to one skilled in the art to modify the braided tubular structure in Steen by substituting hollow tubular members for the conductive wires as suggested by Mische where conductive tubing is interchangeable with conductive wires in catheter uses...

Final Office Action dated June 15, 2005, page 3, emphasis added. Appellant respectfully disagrees and submits that the requisite teachings or suggestion/motivation for making such a combination is absent from the cited references or elsewhere in the record for at least the below stated reasons.

First, Appellant respectfully submits that the Examiner's primary rationale and alleged motivation for combining the cited references appears to be based on mischaracterization and overstatement of the teachings of Mische. In particular, nothing in the Mische reference or elsewhere supports Examiner's argument that, in general, selectively replacing solid conductive wires with hollow tubes is "old and well known", or that hollow tubing is broadly and generally interchangeable with conductive wires in an unlimited variety of medical catheters. The Examiner has provided no reasoning or cited any support for this position, and Appellant's detailed review of the Mische reference was unable to find any support for the Examiner's characterization of the art.

Mische teaches a method and structure for producing an electrical interconnect cable which is a single, multiconductor cable having conductors ("micro-cables") of precisely controlled spacing, and constructed for connection to interconnect zones of an integrated circuit and positioning in an interior lumen of a diagnostic catheter. According to the primary

embodiments of Mische, the conductor wires consist of solid metal or glass micro-cables for electrical or optical signal transduction. In contrast to the Examiner's characterization, Mische merely teaches an alternate embodiment where the interconnect cable includes hollow tubes or "micro-tubes" or a combination of micro-tubes and conductor wires. Nothing in Mische, however, suggests a broad and general desirability of hollow tubes compared to solid conductive wires or that those elements are even "interchangeable", and there is certainly no suggestion that selectively replacing solid conductive wires with hollow tubes, in any context, is "old and well known". Thus, the primary basis for the alleged motivation to combine and, therefore, the rejection in general, completely lacks support in the cited references.

Second, the Examiner additionally argues that motivation is found in this case since substituting conductive wires in Steen with hollow tubes of Mische would provide "another means to transmit something from one end of the catheter to the other which would expand the usefulness of the product and thereby make it more valuable to the user thereby saving money by providing a more versatile catheter." Final Office Action dated June 15, 2005, page 3. Appellant respectfully disagrees. The purpose of the interconnect cable of Mische is to provide for signal transduction in a diagnostic catheter lumen in the first place, not to provide "another means" of material transportation (rather than signal transduction) in a different or unrelated device as suggested by the Examiner. In contrast to Mische, Steen provides a hollow lumen catheter having a conventional braid reinforcement. The hollow lumen of Steen is designed for material transport or access, and there is no teaching or suggestion whatsoever in Steen that further lumen(s) are necessary or desirable, or even remotely contemplated, for any purpose. Furthermore, the record is completely devoid of any teaching or suggestion to "expand the usefulness" of the Steen catheter. Thus, the modification proposed by the Examiner lacks the requisite suggestion or motivation, but instead appears instead to be a result of impermissible hindsight construction based primarily on the Appellant's disclosure, rather than the cited references or in the knowledge in the art.

Thus, besides lacking the broad teachings alleged by the Examiner, neither of the references, alone or in combination, specifically teach or even remotely provide a suggestion or motivation for having a braided tubular structure embedded in a wall of a polymeric tubular

member of a catheter body, as recited in claim 1. Nevertheless, the Examiner continues to argue that

> the base reference to Steen discloses a wire that is embedded in the wall of a catheter for transmitting signals from one end of the catheter to the other, the modifying reference to Mische discloses the substitution in catheters of wires used for transmitting signals with hollow tubes also used for transmission, the modification is a mere substitution of one type of transmission wire with a hollow type as taught by Mische...

Advisory Action dated August 8, 2005.

Appellant respectfully submits that the Examiner's argument is entirely misplaced and depends on impermissible hindsight reconstruction using Appellant's disclosure. As the Examiner is certainly aware, the courts have repeatedly instructed that rejection of applications solely by finding prior art corollaries for claimed elements is inappropriate because it essentially would permit an Examiner "to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention." *In re Rouffet*, 47 U.S.P.Q.2d 1453, (Fed.Cir. 1998). In order to prevent impermissible hindsight reconstruction of prior art references based on the Appellant's own disclosure, the Examiner must specifically show a motivation to combine the references in order to establish *prima facie* obviousness. *Id.* *See also, In re Vaeck*, 20 U.S.P.Q.2d 1438 (CAFC 1991).

Appellant has reviewed the references in detail and finds not only is the desired motivation for the proposed combination absent, but that the specific design of the inter-connect cables and teachings of Mische so distinctly differ from both the teachings of Steen and the disclosure of the present invention, such that Mische actually teaches against the combination being made by the Examiner.

In particular, Mische teaches that the interconnect cable is to be specifically positioned inside a catheter lumen, and the only catheters contemplated include diagnostic catheters particularly designed for in vivo sensing of body parameters. In this regard, Appellant points out that in contrast to the solid braid embedded in a catheter wall as taught by Steen, Mische teaches that the interconnect cable is specifically "adapted and designed for insertion into

a catheter 22 lumen." (see, e.g., Mische col 3, lines 1-2). At col. 1, lines 19-21, Mische teaches that the "interconnect's flexible one piece micro-construction allows it to be inserted into the catheter lumen with greater ease and less damage than individual wires." Further, Mische teaches again at col. 2, lines 11-13 "the micro-cable inter-connect, retained within a catheter lumen, in assembly between a sensor and a connector." (emphasis added). Appellant respectfully points out that a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the modification proposed by the Examiner. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q 303 (Fed.Cir. 1983).

Thus, there is no remote suggestion in Mische that the inter-connect cables could find use in either 1) a catheter wall or a braid reinforcement structure in the wall of a medical catheter, or anywhere other than a catheter lumen; and 2) any type of medical catheter other than the diagnostic catheter specifically taught by Mische. In fact, when considering the references in their entirety, Mische actually teaches against making the proposed combination. Accordingly, while the Examiner may point to various elements of the claimed invention in various prior art references, absent a specific and objectively supported suggestion or motivation to combine those elements a specific manner, the case of *prima facie* obviousness fails, as in the present rejection.

Therefore, for at least the reasons set forth above, the combination of references proposed by the Examiner lacks the requisite suggestion or motivation and appears instead to be a result of impermissible hindsight construction based primarily on the Appellant disclosure, rather than the cited references or in the knowledge in the art. Accordingly, the Examiner has not met the burden necessary for establishing *prima facie* obviousness. For at least these reasons, Appellant requests that the rejection of claims 1, 2, 6, and 7 be withdrawn and the claims be allowed.

B. Whether claims 1-9 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Samson (U.S. Patent No. 6,186,978) in view of Mische (U.S. Patent No. 5,052,105).

In the Final Office Action mailed June 15, 2005, claims 1-9 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Samson (U.S. Patent No. 6,186,978) in view of Mische (U.S. Patent No. 5,052,105). Appellant respectfully traverses this rejection.

Appellant respectfully submits that a *prima facie* case of obviousness has not been met in the present case and that no reasonable combination of the cited references would teach or suggest the claimed invention. In particular, Appellant submits that the Examiner has failed to identify any teaching, in the cited references or elsewhere, that would provide the requisite suggestion or motivation to replace the solid braid reinforcement of Samson with hollow microtubes taught by Mische.

Samson teaches a tubular catheter reinforced with a conventional solid braid reinforcement. The catheter body includes an inner and an outer tubing assembly separated by an annular space, with the conventional solid braid reinforcement(s) integrated between the assemblies. The solid braid reinforcement is specifically designed and solely contemplated to provide structural support for the catheter and protection against unwanted kinking of the tubing wall (see, e.g., Samson, col. 4, lines 46-49, 55-64). As acknowledged by the Examiner, nowhere does Samson teach or suggest a braided tubular structure comprising a plurality of component tubular members, as recited in claim 1.

The Examiner attempts to remedy the deficiency of Samson by combining the teachings of Samson with those of Mische. In particular, the Examiner argues the following:

> The patent to Mische discloses that it is old and well known in the art to substitute hollow conductive tubes 19 in place of conductive wires 14, and that such can be used interchangeably in catheters where such are equally useful conductive means. It would have been obvious to one skilled in the art to modify the braided tubular structure [sic] in Samson by substituting hollow tubular members for the solid wires as suggested by Mische where tubing is interchangeable with solid wires in catheter uses...

Final Office Action dated June 15, 2005, page 4, emphasis added. Appellant respectfully disagrees and submits that the requisite teachings or suggestion/motivation for making such a combination is absent from the cited references or elsewhere in the record for at least the below stated reasons.

As above, Appellant respectfully submits that the Examiner's primary rationale and alleged motivation for combining the cited references appears to be based on mischaracterization and overstatement of the teachings of Mische. In particular, nothing in the Mische reference or elsewhere supports Examiner's argument that, in general, selectively replacing solid conductive wires with hollow tubes is "old and well known", or that hollow tubing is broadly and generally interchangeable with conductive wires in an unlimited variety of medical catheters. The Examiner's characterization of Mische wholly lacks support in the cited references or elsewhere. Thus, the primary basis for the alleged motivation to combine the cited references and, therefore, the rejection in general completely lacks support in the cited references.

Appellant further points out that the solid braid reinforcement of Samson is specifically designed and used solely for structural support, not for conducting electricity and, therefore, there would be no reason or motivation to replace the solid braid reinforcement of Samson with an "equally useful conductive means". While the solid braid reinforcement of Samson may include metal (i.e., an electrically conductive element), the reinforcements are support structures for protection against unwanted kinking of the tubing wall. In operation of the Samson device, fluid is passed through the annular space, in contact with the interstices of the solid braid reinforcement structure, and into the balloon (see, e.g., Samson, col. 5, lines 1-3). Transmission of an electrical current through the solid braid reinforcement is neither contemplated by Samson, nor is it plausible due to the configuration of the catheter device (e.g., fluid contacting the solid braid reinforcement structure). Thus, there could be no reason or motivation to replace the braided support of Samson with another "equally useful conductive means" because the solid braid reinforcement as contained in the device of Samson is not suitable for conducting electricity in the first place.

The Examiner additionally argues that motivation is found in the present case since replacing the solid braid reinforcement of Samson with the hollow tubes of Mische would provide "another means to transmit something from one end of the catheter to the other which would expand the usefulness of the product and thereby make it more valuable to the user thereby saving money by providing a more versatile catheter." Final Office Action dated June 15, 2005. Applicants respectfully disagree. As set forth above, the purpose of the inter-connect cable of Mische is to provide for signal transduction in a diagnostic catheter lumen in the first place, not to provide "another means" of material transportation in a different or unrelated device as suggested by the Examiner. In contrast to Mische, the Samson device already includes a lumen catheter with a hollow annular space, both of which are designed for material transport or access. Moreover, there is no teaching or suggestion anywhere in Samson that additional lumen(s) are necessary or desired, or even remotely contemplated, for any purpose. Other than the Appellant's own disclosure, the record is completely devoid of any teaching or suggestion to "expand the usefulness" of the Samson catheter. Therefore, as above, the modification proposed by the Examiner lacks the requisite suggestion or motivation, but instead appears to be a result of impermissible hindsight construction based primarily on the Appellant's disclosure, rather than the cited references of knowledge in the art.

Thus, not only to the cited references lack the teachings alleged by the Examiner, but neither of the references, alone or in combination, teach or even remotely provide a suggestion or motivation for having a braided tubular structure embedded in a wall of a polymeric tubular member of a catheter body, as required by claim 1. A detailed review of the references finds that not only is the desired motivation for the proposed combination absent, but that the cited references consistently and clearly teach against the combination being made by the Examiner.

As set forth above, there is no suggestion in Mische that the inter-connect cables could find use in either 1) a catheter wall or a braid reinforcement structure in the wall of a medical catheter, or anywhere other than a catheter lumen; and 2) any type of medical catheter other than the diagnostic catheter specifically taught by Mische. In fact, when considering the

references in their entirety, Mische actually teaches against embedding the micro-tubes of Mische in a catheter wall.

Moreover, the fact that the solid braid reinforcement of Samson is specifically designed and used for increasing structural integrity of the catheter further teaches away from the Examiner's suggested replacement of the solid braid of Samson with hollow wires because such a modification would actually reduce the tensile strength of the braid, thereby reducing the structural support desired by Samson in the first place. Appellant again points out that a prior art reference must be considered in its entirety, including portions that would lead away from the modification proposed by the Examiner. *W.L. Gore*, 220 U.S.P.Q 303 (Fed.Cir. 1983). Thus, the combination argued by the Examiner again appears to result from impermissible hindsight reconstruction based purely on the teachings of the present invention, and lacks support in the sighted references.

In addition to relying on novel and non-obvious independent claim 1, dependent claims 8 and 9 recite specific elements of the invention not disclosed in the art. For example, depended claim 8 further requires where said plurality of component tubular members longitudinal lumens are fluidly connected to a plenum at least one of the distal and proximal ends. Dependent claim 9 further includes a balloon on the catheter body connected to exchange inflation media through the lumens of the braided tubular structure. As discussed above, no reasonable combination of the cited references would teach or suggest a catheter having a braided tubular structure comprising a plurality of component tubular members, each having longitudinal lumens, woven radially in and out to form the braided tubular structure, wherein the braided tubular structure is embedded in a wall of a polymeric tubular member, as recited in claim 1, much less a plurality of component tubular members fluidly connected to a plenum or a balloon catheter connected to exchange inflation media through the lumens. The teachings of Samson are limited to solid braid reinforcement and Mische does not teach a plenum or a balloon in any context. Hence, claims 8 and 9 are further allowable over the cited references.

Therefore, for at least the reasons set forth above, the combination of references proposed by the Examiner lacks the requisite suggestion or motivation and appears instead to be

a result of impermissible hindsight reconstruction based on the Appellant's disclosure, rather than the cited references or knowledge in the art. Accordingly the Examiner has not met the burden necessary for establishing *prima facie* obviousness. Appellant points out that the Examiner bears the initial burden of factually establishing and supporting any *prima facie* conclusion of obviousness. MPEP § 2142. If the Examiner does not produce a *prima facie* case, the Appellant is under no obligation to submit evidence of nonobviousness. *Id.* In the instant case, the Examiner has not pointed to any evidence in the cited art references, or knowledge of those skilled in the art, that would provide a suggestion or motivation to combine the reference teachings of Samson with Mische so as to produce the catheter of claims 1-9.

Accordingly, for the reasons set forth above, *prima facie* obviousness has not been established and withdrawal of the rejections of claims 1-9 under 35 U.S.C. § 103(a) is respectfully requested.

9. CONCLUSION

Appellant believes that the above discussion is fully responsive to all grounds of rejection set forth in the Final Office Action dated June 15, 2005. For the reasons set forth above, it is respectfully submitted that the rejection should be reversed.

If for any reasons the Examiner believes a telephone conference would in any way expedite resolution of the issues raised in this appeal, the Examiner is invited to telephone the undersigned at 206-467-9600.

Respectfully submitted,

Date: 8/30/2006

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10. APPENDIX A CLAIMS

1. (Previously presented) A catheter comprising;

a catheter body comprising at least one polymeric tubular member; and

a braided tubular structure comprising a plurality of component tubular members each having longitudinal lumens, woven radially in and out to form said braided tubular structure, wherein said braided tubular structure is embedded in a wall of the polymeric tubular member.

2. (Previously presented) The catheter of claim 1, wherein the component tubular members are comprised of polymeric tubing.

3. (Previously presented) The catheter of claim 1, wherein the component tubular members are comprised of metallic tubing.

4. (Previously presented) The catheter of claim 3, where the metallic tubing comprises a superelastic alloy.

5. (Previously presented) The catheter of claim 4, wherein the superelastic alloy comprises nickel and titanium.

6. (Previously presented) The catheter of claim 1, wherein the at least one polymeric tubular member is disposed over said braided tubular structure.

7. (Previously presented) The catheter of claim 6, wherein said catheter body is of a size and shape suitable for introduction into a human blood vessel.

8. (Previously presented) The catheter of claim 1, where said plurality of component tubular members longitudinal lumens are fluidly connected to a plenum at least one of the distal and proximal ends.

9. (Previously presented) The catheter of claim 1, further comprising a balloon on the catheter body connected to exchange inflation media through the lumens of the braided tubular structure.

11. APPENDIX B EVIDENCE

None.

12. APPENDIX C RELATED PROCEEDINGS

None.